

### **REMARKS**

This Amendment is responsive to the Office Action mailed January 3, 2008 and the Advisory Action mailed October 31, 2008. Filed concurrently herewith is a Request for Continued Examination. After entry of this Amendment, claims 1 and 14-34 are currently pending in this application and subject to examination. Claims 2-13 are cancelled without prejudice or disclaimer. Claim 1 is amended. New claims 14-34 are added. No new matter has been added.

Claim 1 is amended to delete the subject matter pertaining to modified, unsubstituted starch products for clinical use. This subject matter has been presented as a separate independent claim, new claim 27. Cancelled dependent claims 2 and 4-9 are presented as new claims 15 and 17-21, which all ultimately depend from amended claim 1, and as new claims 28-30, which depend from new claim 27. Cancelled independent claims 10-13 are presented in dependent form as new claims 23-26, which all ultimately depend from amended claim 1, and as new claims 31-34, which depend from new claim 27. Support for the amendment to claim 1 and for new claims 15 and 17-34 is found in the claims as originally filed. Support for the limitations in new claims 14 and 16 is found at page 5, lines 2-9; page 5, line 35 to page 6, line 20; and in the Example on page 10, line 38 of the present specification.

Reconsideration of the application as amended is respectfully requested in view of the following remarks.

#### **Rejection Under 35 U.S.C. § 103(a)**

Claims 1, 2, 5-8, 11, and 13 stand rejected as obvious over U.S. Patent No. 5,218,108 to Sommermeyer et al. (hereinafter "Sommermeyer II") in view of U.S. Patent Application Publication No. 2002/0065410 to Antrim (hereinafter "Antrim"). Claims 1, 2, 4, 6-8, 10, and 12 stand rejected as obvious over U.S. Patent No. 6,284,140 to Sommermeyer et al. (hereinafter "Sommermeyer III") in view of Antrim. Claim 9 stands rejected as obvious over either of

Sommermeyer II or Sommermeyer III, both in view of Antrim and in further view of WO 00/33851 A1 to Naggi et al. (hereinafter "Naggi"). Applicants respectfully traverse.

#### **Rejection of Claims 1, 2, 5-8, 11, and 13**

Since claims 2, 5-8, 11 and 13 are cancelled, this rejection is considered moot as it pertains to those claims. Applicants maintain that claim 1, as amended, is non-obvious and patentable over the combined teachings of Sommermeyer II and Antrim for the reasons presented in Applicants' November 13, 2007 and October 2, 2008 Amendments and in the Declaration of Dr. Henning and incorporate those remarks herein by reference in their entirety. Applicants respectfully request withdrawal of this rejection.

#### **Rejection of Claims 1, 2, 4, 6-8, 10, and 12**

Since claims 2, 4, 6-8, 10 and 12 are cancelled, this rejection is considered moot as it pertains to those claims. Applicants maintain that claim 1, as amended, is non-obvious and patentable over the combined teachings of Sommermeyer III and Antrim for the reasons presented in Applicants' November 13, 2007 and October 2, 2008 Amendments and in the Declaration of Dr. Henning, incorporated herein by reference in their entirety. Applicants respectfully request withdrawal of this rejection.

#### **Rejection of Claim 9**

Since claim 9 is cancelled, this rejection is considered moot.

#### **New Claims 14-26**

New claims 14-22 are directed to modified hydroxyethyl- or hydroxypropyl-substituted starch products for clinical use. New claim 23 is directed to a dialysis solution comprising such modified hydroxyethyl- or hydroxypropyl-substituted starch products. New claim 24 is directed to a plasma expander comprising such modified hydroxyethyl- or hydroxypropyl-substituted starch products. New claim 25 is directed to a method of peritoneal dialysis using a dialysis solution comprising such modified hydroxyethyl- or hydroxypropyl-substituted starch products.

New claim 26 is directed to a method of volume replacement using a plasma expander comprising such modified hydroxyethyl- or hydroxypropyl-substituted starch products. The modified hydroxyethyl- or hydroxypropyl-substituted starch products of these claims *have a degree of branching in the range of from 8 to 10 mol %*.

It is the position of the Applicants that new claims 14-26 are non-obvious and patentable over the cited references, either alone or in combination, for the reasons presented in Applicants' November 13, 2007 and October 2, 2008 Amendments and in the Declaration of Dr. Henning, incorporated herein by reference in their entirety. Furthermore, it is the position of the Applicants that the data of unexpectedly superior storage effects presented in the Declaration of Dr. Henning is at least commensurate in scope with new claims 14-26 inasmuch as the degree of branching of these claims is limited to a range of from 8 to 10 mol %. This data of unexpectedly superior storage effects is, in particular, at least commensurate in scope with new claim 16 inasmuch as the degree of branching of this claim is limited to a range of from 8 to 10 mol % *and* the degree of substitution MS is limited to a range of from 0.05 to 0.15. New claims 14-26 are non-obvious and patentable over the cited references, either alone or in combination with each other, and Applicants respectfully request their allowance.

#### **New Claims 27-34**

New claims 27-30 are directed to modified *unsubstituted* starch products for clinical use. New claim 31 is directed to a dialysis solution comprising such modified unsubstituted starch products. New claim 32 is directed to a plasma expander comprising such modified unsubstituted starch products. New claim 33 is directed to a method of peritoneal dialysis using a dialysis solution comprising such modified unsubstituted starch products. New claim 34 is directed to a method of volume replacement using a plasma expander comprising such modified unsubstituted starch products. To establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *See* MPEP § 2143.03 (citing *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Sommermeyer II, Sommermeyer III, Antrim, and Naggi, either alone or in combination, fail to teach or suggest the use of *unsubstituted* starches having the claimed features. As such, new claims 27-34 are non-obvious

and patentable over these references, either alone or in combination with each other, and Applicants respectfully request their allowance.

In view of the foregoing amendment and remarks, Applicants believe the pending application is in condition for allowance.

Filed concurrently herewith is payment in the amount of \$2184 to cover (1) the RCE fee required by 37 C.F.R. § 1.17(e), (2) the fee required by 37 C.F.R. § 1.17(a)(4) for a 4-month extension of time less the amount previously paid for a 2-month extension of time, and (3) the fee required by 37 C.F.R. § 1.16(i) for two claims in excess of twenty. Should any other fees be required in connection with this amendment, the Director is hereby authorized to charge any fees due or outstanding, including any extension fees, or credit any overpayment, to Deposit Account No. 03-2775, under Order No. 09600-00028-US, from which the undersigned is authorized to draw.

Dated: December 2, 2008

Respectfully submitted,

Electronic signature: /Eamonn P. Morrison/  
Eamonn P. Morrison  
Registration No.: 55,841  
CONNOLLY BOVE LODGE & HUTZ LLP  
1007 North Orange Street  
P. O. Box 2207  
Wilmington, Delaware 19899-2207  
(302) 658-9141  
(302) 658-5614 (Fax)  
Attorney for Applicant